Citation:

Gordon MM, Bopp MJ, Easter L, Miller GD, Lyles MF, Houston DK, Nicklas BJ, Kritchevsky SB. Effects of dietary protein on the composition of weight loss in post-menopausal women. *J Nutr Health Aging.* 2008 Oct;12(8):505-9.

PubMed ID: 18810296

Study Design:

Nonrandomized Clinical trial

Class:

C - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine whether a hypocaloric diet high in protein (> 1.2 g/kg/day) as compared to a lower protein, hypocaloric diet (<0.8 g/kg/day) can prevent the loss of lean body mass that is associated with weight loss in older overweight or obese women.

Inclusion Criteria:

- BMI 25-40 kg/m²
- Waist circumference >36 inches
- Age 50-70
- No menses for at least 1 year
- Non-smoking
- Not on hormone replacement therapy
- Sedentary (<15 minutes exercise two times/week in the past 6 months)
- Weight stable with < 5% weight change in the 6 months prior to enrollment.

Exclusion Criteria:

- Evidence of untreated hypertension (blood pressure> 160/90 mm/Hg)
- Hypertriglyceridemia (triglycerides > 400 mg/dl)
- Insulin-dependent diabetes
- Active cancer, liver, renal, or hematological disease
- Other medical disorders (not specified)

Description of Study Protocol:

Recruitment:

- Women on the low-protein diet (LO-PROT) were a subset of women enrolled in the diet-only group of an on-going clinical trial designed to examine the metabolic effects of a hypocaloric diet with or without exercise.
- Twelve additional women were recruited as a comparison high-protein hypocaloric diet comparison group (HI-PROT).
- Method of recruitment was not discussed.

Design: Nonrandomized clinical trial

- Baseline measurements of body composition and body fat distribution were performed after at least two weeks of weight stability and at least two weeks prior to the beginning of the intervention.
- The participants were asked not to alter their sedentary lifestyle during the study. Individual diets were developed for each participant to elicit an approximate 400 calorie/day energy deficit and participants were provided with meals.
- The HI-PROT group received protein supplements.
- After 20 weeks, the women were retested in the same manner as at baseline. During the study participants were asked to keep a long of everything they ate or drank and records were monitored by a dietitian to verify compliance to the diet.

Blinding used: implied with measurements

Intervention (if applicable):

- All women were provided daily lunch, dinner, and snacks prepared based on each women's choices.
- Participants prepared their own breakfast daily from a menu developed by an RD.
- Women kept a log of everything they ate or drank and those records were monitored by a registered dietitian.
- Each woman in the HI-PRO group was provided a daily protein supplement to help meet protein needs while keeping calorie intake low.

Statistical Analysis:

- The two-sample t test was used to calculate the differences between the LO PROT and HI PROT groups.
- Analysis of covariance was used to evaluate the effect of group on loss of lean body mass adjusting for changes in total fat mass.
- Because the two groups differed with respect to some baseline characteristics, analysis of covariance was used to identify other significant predictors of lean mass change for inclusion in a model.

Data Collection Summary:

Timing of Measurements: Measurements were performed at baseline and after a 20-week intervention.

Dependent Variables

- Percent lean body mass as measured by dual energy x-ray absorptiometry.
- Percent body fat as measured by dual energy x-ray absorptiometry.
- Total body mass as measured by dual energy x-ray absorptiometry.

- Appendicular lean mass (lean mass in the arms and legs) as calculated as the sum of non-bone lean mass in arms and legs.

Independent Variables

- Low protein, low calorie diet (0.5-0.7 g protein/kg/day). Calorie needs were estimated using indirect calorimetry with a diet provided that was a 400-calorie/day deficit to encourage weight loss
- High-protein, low-calorie diet (1.2-1.5 g protein/kg/day). Calorie needs were estimated using indirect calorimetry with a diet provided that was a 400-calorie/day deficit to encourage weight loss.

Control Variables

Description of Actual Data Sample:

Initial N: The study enrolled 15 women in the LO-PROT group and 12 women in the HI-PROT group. The initial n was 27.

Attrition (final N): Three women withdrew from the study, resulting in a final n of 24, 15 in the LO PROT group, 9 in the HI PROT group

Age: Mean age of participants was 58 ± 6.6 years

Ethnicity: Participants were African American or Caucasian. 33.3 percent of the HI PROT group were African American (n=3) and 40 percent of the LO PROT group were African American (n=6).

Other relevant demographics: No information was provided on SES or education of participants.

Anthropometrics: The HI PROT vs LO PROT groups had differences in BMI (31.7 vs 33.8 kg/m²), Total Body Mass (85.5 vs 93.5 kg), Total Lean Body Mass (47.2 vs 51.4 kg), and Total Fat mass (36.3 vs 39.8 kg).

Location:Winston-Salem, NC

Summary of Results:

Key Findings:

- The absolute amount of total body mass lost was slightly, but not significantly, greater in the LO PROT group.
- The relative amount of total body mass lost was similar between groups.
- The amount of fat mass lost was similar between groups.
- The LO PROT group lost approximately twice the absolute amount of total lean mass and appendicular lean mass than the HI PROT group. When the loss of lean mass was expressed as a percentage of total mass lost, the relative loss of lean mass is the HI PROT group was substantially less than in the LO PROT group.
- The higher-protein diet was associated with retained lean mass across the range of fat loss.

Comparison of results

Changes in Body mass measurements after 20 weeks	LO-PROT	HI-PROT	p value
Lean Body Mass lost	4.1±2.0 kg	2.1±1.8kg	0.02
Total Body mass lost	11.2±3.8	8.4±4.5	0.12
Fat mass lost	7.0±3.0	6.3±3.0	0.55
Appendicular Lean Mass	2.3±1.4	1.1±0.7	0.03
Lean body mass as a % of total body mass	37.7±14.6	17.3%±27.8	0.03

Author Conclusion:

The amount of dietary protein intake is an important modifiable factor modulating the degree of lean body mass during voluntary weight loss. Failure to maintain total protein intake during weight loss can lead to unnecessarily large changes in lean body mass, which can increase risk for mortality and disability.

Reviewer Comments:

- *The n in this study was very small.*
- *The two study groups had differences in baseline BMI, Total Body Mass, Lean Body Mass, and Total fat mass. Analysis of covariance was used to identify other significant predictors of lean mass change for inclusion in a model, but because the sample size is so small the reviewer is concerned that this was not valid.*
- *Study participants were asked not to alter their sedentary lifestyles during the 20-week study. There was no information provided on how physical activity (or lack there-of) was monitored. Changes in exercise patterns or changes in other activities at home or work over a 20-week period could contribute to increases or decreases in lean body mass that do not appear to be accounted for in this study.*
- *All three of the subjects that dropped out of this study were in the Hi PROT group (n was 12 initially, 9 at completion). This reflects a 25% withdrawal for this group while the LO PROT group had no subjects that withdrew from the study.*
- *It is unclear to this reviewer how the 12 women in the HI-PROT group were recruited so it is not clear if they were a representative sample of the population.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes

3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	No
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	No
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	No
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	???
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A

3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	No
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A

6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	???
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	???
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes

10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes